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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/311,837	05/14/1999	THOMAS E. BARTA	MON-116.6	1791
24628	7590	07/28/2004	EXAMINER	
WELSH & KATZ, LTD 120 S RIVERSIDE PLAZA 22ND FLOOR CHICAGO, IL 60606			CHANG, CELIA C	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/311,837

Applicant(s)

BARTA ET AL.

Examiner

Celia Chang

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 20 May 2004.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) See Continuation Sheet is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) 52-65,67-71,82-85,87-94 and 148-153 is/are allowed.
6) ☐ Claim(s) 7-16,20-22,26-28,35-42,147,154,156,157,161,163 and 164 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 7-16,20-22,26-28,35-42,52-65,67-71,82-85,87-94,128-131 and 147-164.

DETAILED ACTION

1. This application is RCE of SN 09/311,837. Claims 1-6, 17-19, 23-25, 29-34, 43-51, 66, 72-81, 86, 95-127, 132-146 have been canceled. Claims 162-164 are newly added. Claims 7-16, 20-22, 26-28, 35-42, 52-65, 67-71, 82-85, 87-94, 128-131, 147-164 are pending.

2. Claims 128-131, 154, 156, 161, 164 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 128-131, 154, 156, 161, 164 are self conflicting because these are pharmaceutical composition claims without any dosage limitation. Please note that pharmaceutical compositions can neither be non-effective nor toxic. Therefore, it is recommended that the “therapeutically effective” amount of the active compound be incorporated into the claims.

3. Claims 7-16, 20-22, 26-28, 35-42, 147, 157, 163 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while provided written description and enablement for treating corneal ulceration, does not reasonably provide written description and enablement for the scope as claimed encompassing any and all pathological conditions treatable by inhibiting matrix metalloprotease activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to operate the invention commensurate in scope with these claims. The scope encompassed all pathological conditions treatable by inhibiting matrix metalloprotease activity is reach through to claim the scope of the future discovery in pathological conditions that linked or related to the inhibition of matrix metalloprotease activity.

The specification has been evaluated for adequacy in specific enabling disclosure according to the requirement as stated in the MPEP 2164.01(a) “There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is “undue”. The factors to be considered herein are those set forth as the In re Wands, 8 USPQ 2nd 1400 (1988) decision.

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Nature of invention and The state of the art and predictability

The claims are drawn to method of treating undetermined conditions by inhibiting MMP enzyme. Enzyme inhibition not only is highly unpredictable, the variation of possible enzyme system being involved is also enormous (see p.1-3 MMP 1, 2,MMP11).

The amount of guidance and working examples


It is noted that in the specification no specific guidelines were found for how to pick and choose a compound for any particular pathology except for those disclosed in example 447 for treating corneal ulceration. The specification particularly noted that (p.1-5) many classes of MMP inhibitors may be related to different function in a living system and many enzymes and tissues are involved in MMP activity. In view of the complexity of MMP functionality and the enormous variation of MMP subclasses of inhibitory function, the lack of explicit guidance in how to pick and choose the large number of compounds for treating undetermined, including not yet discovered, disorders or pathology involving inhibiting MMP, the specification lacks adequate disclosure in how to make and use of the claimed process. The standard for 112 is that the specification itself to inform not for others to find out for themselves. *Exparte Dash* 27 USPQ2d 1481, 1488.

4. Compound claims 52-65, 67-71, 82-85, 87-94, 148-153, 155, 158-160, 162 are allowable.
5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
July 24, 2004


Celia Chang
Primary Examiner
Art Unit 1625